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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,775	08/14/2001	Brian Ronald Davis	40158.1USI3	2234
23552	7590	03/10/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			NGUYEN, DAVE TRONG	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 03/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

SMA

Office Action Summary**Application No.**

09/767,775

Applicant(s)

DAVIS ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/4/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-13, 16-43, drawn to a non-viral modification method of using a single stranded end-capped oligo, cells comprising the oligo, classifiable in class 435, subclass 6, subclass 325.

Group II. Claims 14-15, drawn to a transgenic animal, classifiable in class 800, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II are distinct because inventions I-II are directed to distinct materials.

The claimed invention of group I is not drawn in any way to or to make a transgenic animal, and *vice versa*. Further, Invention II is distinct from invention I because the transgenic animal of Group II does not necessarily contain a single stranded end capped oligo, and can be made by other known methods such as ES or nuclear transfer method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

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Should invention I be elected, a Species Restriction to one of the following inventions is required under 35 U.S.C. 121:

The presently pending claims for each of the elected invention are generic to a plurality of disclosed patentably distinct species comprising:

- A specific species of a cell line as listed in claim 10,
- A specific species a target population of cells, as listed in claim 17.
- A specific species of an incorporation step as listed in claims 19.
- A specific species of an identifiable genetic mutation as listed in claims 21-27, and 30-36.
- A specific species of a substrate for attachment as listed in claim 43.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from each of the respective group of species as listed and cited above, even though this requirement is traversed. The combined features of a particular active agent and/or cytokine and/or carrier, for example, are distinct structurally and would not necessarily overlap with one another when a prior art search is conducted.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Sequence Rules 1.821

The specification is objected under Sequence Rules 1.821 because the specification does not conform to the requirements of 37 CFR 1.821 because claim 28 contain DNA sequences for which there is no indicated SEQ ID NO:___ identifier for the DNA sequences. Additionally, it is often convenient to refer to DNA sequences in any of the disclosed figures by SEQ ID NO: identifier. Thus, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a) (2). Correction is required before this claim can be examined properly and completely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(571-272-0731)**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson* may be reached at **571-272-0184**

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Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
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A handwritten signature in black ink, consisting of a stylized 'D' followed by a horizontal line.

DAVE T. NGUYEN
PRIMARY EXAMINER